

EPA Registration No.
352-902
Vol. 3

PROCESSING REQUEST

Reg # 352-902

Decision # 434657

Description: Storage Stability And Corrosion Characteristics

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☒ Dated: 12/11/17

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Mengon Adams

Division: BPPD

Phone: 703-347-8496

Date: 12/11/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 11, 2017

Ms. Patricia G. Devine
MANAGER, US REGISTRATION, DUPONT CROP PROTECTION
E.I. DuPont De Nemours and Company
CHESTNUT RUN PLAZA (CRP 720/2E5)
974 CENTRE RD.
WILMINGTON, DE 19805

Subject: E. I DuPont De Nemours and Company's Response to Storage Stability and Corrosion
Characteristics Terms of Registration

Product Name (EPA Registration Number)	Application Date	EPA Receipt Date	Term(s) of Registration (Guideline No.)	OPP Decision Number
Refined Oil Nepeta Cataria 7% Lotion 352-902	August 11, 2016	August 12, 2016	Storage Stability (Guideline No. 830.6317)	434657
			Corrosion Characteristics (Guideline No. 830.6320)	

Dear Ms. Devine:

On July 29, 2009 the U.S. Environmental Protection Agency (EPA) issued a Registration Notice for Refined Oil Nepeta Cataria 7% Lotion (EPA Reg. No. 352-902). Term #2 of the Registration Notice required that DuPont Chemical Solutions Enterprise provide acceptable studies to the EPA within 12 months.

On August 12, 2016, the EPA received data from E. I DuPont De Nemours and Company that responded to the data terms of the Registration Notice. In a memorandum dated September 07, 2017, the EPA rated the storage stability and corrosion characteristics (MRID Nos. 499934-01 & 481062-01) data as acceptable. Thus, you have fulfilled Term #2 of the July 29, 2009, Refined Oil Nepeta Cataria 7% Lotion Registration Notice.

The results indicate that for Refined Oil of Nepeta Cataria 7% Lotion formulation is stable and no physical changes and no corrosion evidence in the stored containers during the 12-month test period at storage condition 25°C and 50% relative humidity.

Page 2 of 2
EPA Reg. No. 352-902
OPP Decision No. 434657

If you have any questions, please contact Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew C. Bryceland". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

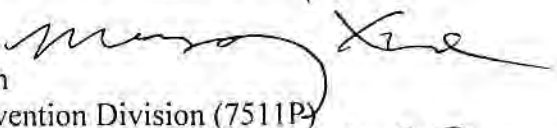
Enclosure


**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES****MEMORANDUM****DATE:** September 7, 2017**SUBJECT:** Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion Formulations (EPA Reg. #s: 352-902, 352-903 and 352-904), Containing 7% and 15% of Nepeta Cataria Oils (Active Ingredient), Respectively. Review of Storage Stability and Corrosion Characteristics

Decision Number: 434657, 434659 & 434660
Submission Nos.: 990394, 990395 & 990396
EPA Reg. #: 352-902, 352-903 & 352-904
Chemical Class: Biochemical
PC Code: 004801
Active Ingredient Tolerance Exemptions: 40 CFR 180.
MRIDs: 48106201 and 49993401

FROM: Manying Xue, Chemist /s/ 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

Through Russell S. Jones, Ph.D., Senior Biologist /s/ 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

Action Requested:

DuPont Crop Protection has submitted studies of storage stability and corrosion characteristics in support of registration of Refined Oil of Nepeta Cataria 7% Lotion (EPA Reg. #: 352-902), Refined Oil of Nepeta Cataria 7% Liquid (EPA Reg. #: 352-904) and Refined Oil of Nepeta Cataria 15% Lotion (EPA Reg. #: 352-903), containing 7 and 15% of Nepeta Cataria Oils (Active Ingredient), respectively.

BPPD has examined the submitted studies of storage stability and corrosion characteristics. The decisions are made to reflect the current OCSPP's policies.

Recommendations and deficiencies are noted below:

1. The submitted studies of storage stability and corrosion characteristics for Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations (EPA Reg. #s: 352-902, 352-903, 352-904) are **ACCEPTABLE**. Results indicate that Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations are stable and no physical changes and no corrosion evidence in the stored containers during the 12-month test period at storage condition of 25°C and 50% relative humidity.

Study Summaries

One-year storage stability and corrosion characteristics have conducted for Refined Oil of Nepeta Cataria 7% Lotion (EPA Reg. #: 352-902), Refined Oil of Nepeta Cataria 7% Liquid (EPA Reg. #: 352-904) and Refined Oil of Nepeta Cataria 15% Lotion (EPA Reg. #: 352-903). Samples of the test substances were packaged in bottles identical in materials and construction to the commercial containers in which the product is expected to be packaged. The containers used were glass and high density polyethylene (HOPE) for the formulation samples. The Technical and Manufacturing Grade samples were packaged in glass, HOPE, and aluminum.

Each container was identified with its contents by reference number. The samples were stored in a Caron 6010 environmental chamber at 25°C and 50% relative humidity for the intended storage duration (3 months, 6 months, and 12 months), and then removed from storage, weighed, visually inspected, and the test substance assayed.

Test Substance

Refined Oil of Nepeta Cataria 7% liquid formulation,
Refined Oil of Nepeta Cataria 15% liquid formulation,
Refined Oil of Nepeta Cataria 7% lotion formulation,
Refined Oil of Nepeta Cataria 15% lotion formulation.

Analytical Method

See CONFIDENTIAL APPENDIX for details.

Evaluations of Corrosion Characteristics

Corrosion characteristics were evaluated based upon changes in visual observations of the containers and closures following storage. At each observation time, the containers and closures were inspected inside and outside for perforations, dents, degradation of the seal or cap, and leaks. Two bottles were evaluated after storage for 3 months, 6 months, and 12 months. Six bottles were evaluated after storage for 12

months. Results are indicated in Tables 1-2.

Table 1. Analysis of Storage Stability of 7% and 15% of Nepeta Cataria Liquid Formulations and Physical observations of Corrosion characteristics (Diluted Samples)

Test period (Month)	7% of Nepeta Cataria Liquid AI Avg. Wt. ¹ & (% Recovery)	7% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery)	15% of Nepeta Cataria Liquid AI Avg. Wt. & (% Recovery)	15% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery)	Physical Appearance
0	6.32	14.0	6.38	14.86	No changes with visual observation for corrosion characteristics
3	6.17 (97.63)	13.76 (98.29)	5.89 (92.32)	13.17 (86.63)	
6	6.85 (108.39)	15.46 (110.43)	6.81 (106.74)	15.48 (104.17)	
12	6.59, 6.50 (103.56)	14.20, 15.46 (105.93)	6.13, 6.08 (95.69)	14.07, 14.41 (95.83)	

¹ Each data point was calculated from six sample analysis.

Table 2. Analysis of Storage Stability of 7% and 15% of Nepeta Cataria Liquid Formulations and Physical observations of Corrosion characteristics (Prepared Samples)

Test period (Month)	7% of Nepeta Cataria Liquid AI Avg. Wt. ¹ & (% Recovery)	7% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery)	15% of Nepeta Cataria Liquid AI Avg. Wt. & (% Recovery)	15% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery)	Physical Appearance
0	7.24	15.72	6.68	15.51	No changes with visual observation for corrosion characteristics
3	6.79 (93.40)	15.28 (97.20)	6.26 (93.71)	13.73 (88.52)	
6	7.29 (100.69)	16.06 (102.16)	6.66 (99.70)	15.35 (98.97)	
12	6.86, 6.77 (94.13)	14.95, 14.20 (95.90)	6.50, 6.45 (96.93)	14.44, 14.87 (94.49)	

¹ Each data point was calculated from six sample analysis.

Conclusion

The submitted studies of storage stability and corrosion characteristics for Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations (EPA Reg. #s: 352-902, 352-903, 352-904) are **ACCEPTABLE**. Results indicate that for Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations are stable and no physical changes and no corrosion evidence in the stored containers during the 12-month test period at storage condition (25°C) and 50% relative humidity.

cc: M.Adams; BPPD Chron File; OHAD/ARS

M. Xue, BPPD, 09/7/2017

~~CONFIDENTIAL APPENDIX~~Analytical Method

Gas Chromatography (GC) utilizing a Flame Ionization Detector (FID) was used in these analyses. The samples to be analyzed were the refined oil of Nepeta cataria, also called Hydrogenated Catnip Oil (HCO) made up in either a liquid or a lotion formulation. The methods E108324-119, "Gas Chromatograph Method for the analysis of Hydrogenated Catnip Oil (HCO) in Formulations" and E108324-122, "Gas Chromatograph Method for the analysis of Hydrogenated Catnip Oil (HCO)" were followed for these analyses.

A solution of the formulation sample containing a known amount of the internal standard, 1,2-dibromobenzene, is analyzed by gas chromatography (GC) for the weight percent of each of the active ingredients in the liquid or lotion formulations or in the Technical and Manufacturing Grade, employing a DB-FFAP column and Flame Ionization Detector (FID). The weight percent of each component is determined by comparisons to calibration curves (peak area ratio vs. amount ratio) prepared from the analysis of standard solutions.

The sample preparation for the liquids consisted of accurately weighing three separate portions of the sample from a given container and mixing with an appropriate amount of Internal Standard Solution. For the lotions, three separate portions were accurately weighed, mixed with an appropriate amount of Internal Standard Solution, and filtered into a sample vial. These sample preparations, called "as prepared" or "neat" were analyzed directly using the GC techniques. These sample preparations were also diluted (1-part test material plus 4 parts solvent for the 7% formulations and 1 part test material plus 9 parts solvent for the 15% formulations) and analyzed using the GC techniques. These sample preparations were called "diluted".

Thus, for a 7% liquid formulation, there were three "neat" samples and three "diluted" samples obtained from any given container. There were a similar number of samples for the other ethanoic liquid and lotion formulations.

The reported results are the average of duplicate analyses of triplicate samples. Standard solutions were prepared from analytical reference standards. The Analytical Standards for analysis of samples were:

Trans-cis Nepetalactone	98%
Dihydronepetalactone 1	99%
Nepetalic Acid 2	85%
Puleganic Acid 1B	96%
Beta-Caryophyllene	99.5%
1,2-Dibromobenzene	98%

Sample Calculation Using Agilent (Hewlett Packard) ChemStation

The chromatographic data processing software of the ChemStation uses peak areas of each component analyzed and an internal standard, 1,2-dibromobenzene, to determine the concentration of the samples. Standard solutions containing known amounts of each component to be analyzed and 1,2-dibromobenzene are first analyzed to create a calibration. The calibration points are constructed by calculating an amount ratio and an area ratio for each level in the calibration table. An equation for the curve through the calibration points is then calculated using linear least squares, and the slope is determined, with the intercept set to zero.

S: 990394

Milestone Element:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Billable: ☐ Yes ☒ No

Tracking

Company: 352 E. I. DU PONT DE NEMOURS AND COMPANY (S)

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 352-902

Product Name: REFINED OIL OF NEPETA CATARIA 7% LOTIC

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 11-Aug-2016



OPP Rec'd Date: 12-Aug-2016



Front End Date: 12-Aug-2016



Risk Manager Send Date: 12-Aug-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Description:

Submission of response to cond data dated 9-1-2010

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content	Des
Study	

View/Edit

July 29, 2009



DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
Newark, DE 19714-0030

August 11, 2016

VIA FEDERAL EXPRESS

Fee For Service: No Fees are proposed for this action, as none are required to submit studies.

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
Document Processing Desk
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Submission of Response to Storage Stability & Corrosion Characteristics Decision #434656 (dated 01-September-2010) for

Refined Oil of *Nepeta cataria* technical; EPA Reg. 352-901 (Formerly 71654-20)
Refined Oil of *Nepeta cataria* 7% Lotion; EPA Reg. No. 352-902 (Formerly 71654-21)
Refined Oil of *Nepeta cataria* 15% Lotion; EPA Reg. No. 352-903 (Formerly 71654-23)
Refined Oil of *Nepeta cataria* 7% Liquid; EPA Reg. No. 352-904 (Formerly 71654-24)
Refined Oil of *Nepeta cataria* 15% Liquid; EPA Reg. No. 352-905 (Formerly 71654-25)

Dear Ms. Hollis:

In May of 2014, the above listed products were transferred from company # 71654 (DuPont Chemical Solutions Enterprise) to company # 352 (DuPont Crop Protection).

In the process of reviewing the products, it was discovered that in September of 2010, company # 71654 received an evaluation of the Storage Stability study (MRID 48106201) submitted in response to the terms and conditions of registration as issued December 4, 2008. This study (OPPTS 830.6317 and 830.6320) was classified as UNACCEPTABLE BUT UPGRADABLE.



DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
Newark, DE 19714-0030

DuPont Crop Protection has determined that no response to this communication was ever submitted by company #71654 prior to the transfer. Therefore, we submit herein a position paper identified as DuPont-47312 in response to the three items identified in the communication to Company # 71654 as per Decision #434656.

A data transmittal and three copies of the following position paper are enclosed:

DuPont-47312	Refined Oil of <i>Nepeta Cataria</i> : Response to Decision # 434656 (Storage Stability and Corrosion Characteristics (MRID 48106201))
--------------	--

Please feel free to contact me at (302) 451-4525 if you have any questions regarding this submission.

Sincerely,

Bonnie J Bieber
U.S. Product Registration Specialist

DATA TRANSMITTAL DOCUMENT

Refined Oil of Nepeta Cataria

Name and Address of Submitter:

E.I. DuPont de Nemours and Company
1090 Elkton Road P.O. Box 30
Newark, DE 19714

Phone (302) 451-4525 (Bonnie J Bieber)

Regulatory Action in Support of Which this Package is Submitted:

Information Submitted in support of continued registration of Refined Oil of *Nepeta cataria*

Product Name:

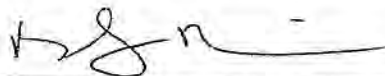
Refined Oil of Nepeta cataria technical; EPA Reg. 352-901 (Formerly 71654-20)
Refined Oil of Nepeta cataria 7% Lotion; EPA Reg. No. 352-902 (Formerly 71654-21)
Refined Oil of Nepeta cataria 15% Lotion; EPA Reg. No. 352-903 (Formerly 71654-23)
Refined Oil of Nepeta cataria 7% Liquid; EPA Reg. No. 352-904 (Formerly 71654-24)
Refined Oil of Nepeta cataria 15% Liquid; EPA Reg. No. 352-905 (Formerly 71654-25)

Transmittal Date: August 11, 2016

List of Submitted Studies:

<u>Data Requirement</u>	<u>Doc Number</u>	<u>Study Title</u>	<u>MRID</u>
NA	DuPont-47312	Refined Oil Of <i>Nepeta Cataria</i> : Response To Decision # 434656 (Storage Stability and Corrosion Characteristics (MRID 48106201))	49993401

Submitter:



Date:

11- AUG-2016

Bonnie J Bieber

U.S. Product Registration Specialist

Company Name: E.I. du Pont de Nemours and Company

PROCESSING REQUEST

Reg # 352 902 Decision # 521893 And 522 873

Description: Amendment to the description of formulation process, basic CSF and label.

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 10/26/16

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 10/04/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Menyan Adams

Division: BPPD

Phone: 703-347-8496

Date: 10/26/16



Refined Oil of *Nepeta cataria* 7% Lotion

INSECT REPELLENT LOTION

Repels Mosquitoes and Black Flies

Active Ingredients

Refined Oil of *Nepeta cataria*

By Weight

7.0%

Other Ingredients

93.0%

TOTAL

100.0%

EPA Reg. No. 352-902

Nonrefillable Container

Net: _____

E. I. du Pont de Nemours and Company
Chestnut Run Plaza, 974 Centre Road
Wilmington, DE 19805

ACCEPTED

10/26/2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for this
pesticide registered under
EPA Reg. No. 352-902

EPA Est. No. _____

Net Contents: _____

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for further treatment advice.

If Swallowed: Call Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing. Discontinue use and consult a doctor if irritation or rash occurs.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the poison control center at 1-800-222-1222. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels mosquitoes and black flies for up to 7 hours.

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds or freshly shaved skin. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin, taking care not to contact the child's fingers and hands.

To apply to face; apply to palms of hand and rub on skin. Do not apply to children's hands.

For continued protection: Reapplication after six hours may be necessary.

After returning indoors, wash treated skin with soap and water or bathe. Also wash clothing before wearing it again.

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal.

PESTICIDE STORAGE: Store away from children

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Never place unused product down any indoor or outdoor drain.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. If empty: Offer for recycling if available or discard in a sanitary landfill. If partly filled: Call your local solid waste agency for disposal instructions.

(NOTE TO REVIEWER: All claims in this section are optional)

- Mosquito repellent
- Blackfly repellent
- Repels mosquitoes
- Repels blackflies
- Effective protection from mosquitoes and black flies
- Effectively repels mosquitoes and blackflies
- (Effective) protection (from a range of mosquitoes and blackflies
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis)
- (diseases)
- Works great on blackflies
- Protection (from bites) from blackflies (for the whole family)
- Protection for people on the go
- Protection that fits your lifestyle
- Protects from mosquitoes and (blackflies) (for up to 7 hours)
- Apply every 6 hours (or as needed)
- Repels mosquitoes and blackflies for up to 7 hours
- (Smart) Outdoor protection (from annoying (mosquitoes) and (black flies) (for up to 7 hours)
- Repels flies (too!)
- Keeps (mosquitoes) off (your family)
- Guards the whole family
- Protection that fits your (active) lifestyle
- Protect(s) your family at dusk and dawn
- An effective insect repellent
- Protection during outdoor activities
- (Sport) (Active) (Outdoor) formula
- Outdoor mosquito and blackfly protection for play and on the go
- For yardwork and camping
- Protects during work, play or recreation
- Contains (a) plant-based repellent
- Contains (a) plant-based Active Ingredient, Refined Oil of Nepeta cataria
- Plant based repellent Active Ingredient, Refined Oil of Nepeta cataria (mosquitoes) (and) (blackflies) for (up to 7 hours)
- Contains plant extracts
- Plant based ingredient
- Contains the insect repellent found in (catmint) (catnip) (oil)
- (Plant based) (insect repellent without trade offs)

- Always carry (product name)
- For playing and relaxing outdoors
- Not oily, greasy or sticky
- No added fragrance
- Contains no dyes (or added fragrances)
- No chemical odor
- No synthetic odor
- No unpleasant odor
- Leaves pleasant feeling on skin
- Won't stain
- (Readily) (Easily) washed off
- Won't harm plastics
- Specially formulated to (feel) (and) (smell) better on your skin
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula
- No residue on skin
- (it's) pleasant smelling
- feel's comfortable
- DEET free
- Non DEET
- Non synthetic
- Readily washed off
- New!
- Repels (mosquitoes) and (blackflies)
- Repels mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis (for up to 7 hours)
- up to 7 hour insect repellent
- up to 7 hour protection
- (Up to) 7 hours of (effective) mosquito protection
- (Up to) 7 hours of protection from mosquitoes. Also (protects against) (works on) (repels)(.) (blackflies)
- Protects for (up to) 7 hours against (mosquitoes) and (blackflies)
- (Protects against) (Fights off) (Repels) (Works on) (mosquitoes) (and) (blackflies)
- Protects against mosquitoes and (blackflies)
- Long-lasting protection against (mosquitoes) and (blackflies)
- Effective protection from mosquitoes
- Effective protection from blackflies
- Stay protected for up to 7 hours (from) (mosquitoes) (and) (blackflies)
- Stay protected for up to 7 hours from mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis
- Proven protection from mosquitoes
- Mosquito protection (for up to 7 hours)
- Biting (mosquito), (black fly) protection that you can feel confident will last up to 7 hours
- Repels mosquitoes (for up to 7 hours)
- Repels blackflies (for up to 7 hours)
- Easy to (Use) (Apply)
- For (hiking) (fishing) (hunting) (camping) (backpacking)
- Relax and enjoy the (outdoors)(.) (the great outdoors)(.) (backyard)(.) (outside)(.) (park)(.) (woods/forest) with up to 7 hours of protection against (mosquitoes) (blackflies)
- Portable repellent protection
- Comfortable feel with no chemical (odor)(smell)
- Comfortable feel with pleasant smell
- Long-lasting
- Contains Refined Oil of *Nepeta cataria*
- Essential oil based repellent, not a synthetic chemical.
- Plant based essential oil insect repellent.
- Essential oil insect repellent with up to 7 hours of effective protection [against] [mosquitoes] [and] [blackflies]
- Insect repellent with up to 7 hours of effective protection (against mosquitoes) (blackflies)

- An essential oil repellent that protects against mosquitoes that may carry West Nile virus
- Repels mosquitoes that may carry West Nile Virus and Encephalitis
- Effective mosquito repellent
- Repels mosquitoes for up to 7 hours, which may carry West Nile Virus and Encephalitis
- Plant based, essential oil that repels mosquitoes for up to 7 hours
- A plant based insect repellent with up to 7 hours of effective protection
- Good for people
- Protects people
- Produced from a renewable resource

D - 1943 102616

LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read this Limitation of Warranty and Liability Before Buying or Using This Product. DuPont will not be responsible for losses or damages resulting from the use of this product in any manner not specifically directed by DuPont. User assumes all risks associated with such non-directed use. If the Terms Are Not Acceptable, Return the Product at Once, Unopened, and the Purchase Price Will Be Refunded.

It is impossible to eliminate all risks associated with the use of this product. Such risks arise from weather conditions, soil factors, off target movement, unconventional farming techniques, presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of DuPont. These risks can cause: ineffectiveness of the product, crop injury, or injury to non-target crops or plants. **WHEN YOU BUY OR USE THIS PRODUCT, YOU AGREE TO ACCEPT THESE RISKS.**

DuPont warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, DUPONT MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL DUPONT OR SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. BUYER'S OR USER'S BARGAINED-FOR EXPECTATION IS CROP PROTECTION. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE EXCLUSIVE LIABILITY OF DUPONT OR SELLER, FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY OR CONTRACT, NEGLIGENCE, TORT OR STRICT LIABILITY), WHETHER FROM FAILURE TO PERFORM OR INJURY TO CROPS OR OTHER PLANTS, AND RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT, OR AT THE ELECTION OF DUPONT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

To the extent consistent with applicable law that allows such requirement, DuPont or its Ag Retailer must have prompt notice of any claim so that an immediate inspection of buyer's or user's growing crops can be made. Buyer and all users shall promptly notify DuPont or a DuPont Ag Retailer of any claims, whether based on contract, negligence, strict liability, other tort or otherwise, or be barred from any remedy.

This Limitation of Warranty and Liability may not be amended by any oral or written agreement.

For product information call: 1-888-6-DUPONT [1-888-638-7668]

Internet address: <http://cropprotection.dupont.com/>

© 2016 E. I. du Pont de Nemours and Company, Chestnut Run Plaza, 974 Centre Road, Wilmington, DE 19805 U.S.A.

All rights reserved.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9-26-16

Experts In-Processing Signature: B.B. Date 9-30-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>352-902</u>		EPA Receipt Date: <u>9-26-16</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X	
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X	
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)					X
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Related: 352-903

Documentation: Pass or Fail

- Certification and Matrices Missing
- CSF marked with 352-903
- Contacted 10/3
- Sent to PM

Inerts: Pass or Fail

- Inerts Approved for Non-Food Use

PRN 11-07: Pass or Fail

- MRID: 500324

10/3/16

Overall Status: Pass or Fail

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BONNIE J. BIEBER
E.I. DUPONT DE NEMOURS AND COMPANY
1090 ELKTON ROAD
P.O. BOX 30
NEWARK, DE 19711

RE: Application for Registration dated: 23-SEP-2016
Date Fee Payment: 26-SEP-2016
Product Name: REFINED OIL OF NEPETA CATARIA 7% LOTION
EPA Registration Number: 352-902
Decision Number: D-521893

Dear Registrant:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f)(4)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected.

There was no Certification with Respect to Citation of Data submitted. There were no Data Matrices submitted. Additionally, the CSF was marked with the incorrect EPA Reg. Number.

Furthermore, pursuant to FIFRA Section 33(b)(2)(G) the Agency must retain 25% of the registration service fee. Any future submissions to the Agency will be considered a new application and subject to the full registration service fee and another initial contents screen of all necessary fees, forms, data, and draft labeling.

Sincerely,

XXXXXXXXX, Director
Office of Pesticide Programs

Varner, Stephanie

From: Varner, Stephanie
Sent: Monday, October 03, 2016 2:04 PM
To: 'bonnie.j.bieber@dupont.com'
Subject: Submission to EPA: REFINED OIL OF NEPETA CATARIA 7% LOTION (EPA Reg. No. 352-902) REFINED OIL OF NEPETA CATARIA 15% LOTION (EPA Reg. No. 352-903)

Dear Ms. Bieber,

My name is Stephanie Varner, and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the products REFINED OIL OF NEPETA CATARIA 7% LOTION (EPA Reg. No. 352-902) REFINED OIL OF NEPETA CATARIA 15% LOTION (EPA Reg. No. 352-903). We have found a few deficiencies with the submissions that will need to be addressed:

1. Please submit a Certification with Respect to Citation of Data for each of the products.
2. Please submit Data Matrices for each of the products.
3. The CSFs appear to be mislabeled in terms of the products and their respective registration numbers:

CSF for REFINED OIL OF NEPETA CATARIA 7% LOTION is marked 352-903 but should be 352-902

CSF for REFINED OIL OF NEPETA CATARIA 15% LOTION is marked 352-902 but should be 352-903

The Pm has requested the applications for these products are be forwarded to them immediately. Please send all requested forms and revisions to them directly.

Thanks!

Stephanie Varner

Contractor, US EPA
2777 S. Crystall Drive, S-4813
Arlington, VA 22202
(703) 347-0240
Email: varner.stephanie@epa.gov

